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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/928,191 | 08/11/2001 | Christophe Schilling | UCSD 99-093 | 6758 |
| 28213 7590 01/26/2007 DLA PIPER US LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133 | | | EXAMINER CLOW, LORI A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 01/26/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--|--|--|
| Office Action Summary | Application No. 09/928,191 | Applicant(s) SCHILLING, CHRISTOPHE | |
| | Examiner Lori A. Clow, Ph.D. | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

Applicants' response, filed 13 November 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-8 and 10-15 are currently pending. Claims 9 and 16-27 have been cancelled. Claims 10-15 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Applicant is reminded that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Specification

The disclosure is objected to because of the following informalities: The specification, at page 25, line 32, contains inserted text that appears to not be part of the disclosure (see text in parenthesis beginning "XXX").

Appropriate correction is required.

Claim Rejections - 35 USC § 101-Non-Statutory Subject Matter

35 U.S.C. 101 reads as follows:

Art Unit: 1631

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons set forth in the previous Office Action.

Response to Applicant's Arguments

1. Applicant argues that "claimed subject matter does not require transformation of an article or physical object into a different state or thing in order to satisfy the requirement of §101".

As has been stated in the previous Office Action, the claims, as a whole, must satisfy section 101 and must be for a practical application, which is defined as: the claimed invention must transform an article to a different state or thing OR the claimed invention must otherwise produce a useful, concrete, and tangible result. Therefore, it is agreed that "transformation" alone is not the only criteria to assess statutory subject matter, as was set forth in the previous Office Action. As was also set forth, the claims do not provide a physical transformation because they are drawn only to method steps in which reactions of a network are constructed from biochemical data, mathematical manipulations, and determination of flux. These steps are merely manipulations of abstract ideas and therefore, do not provide for a transformation step.

Therefore, the claims must be assessed for providing a concrete, tangible, and useful result. As was stated, the claims do not provide a specific result which meets the concrete, tangible, and useful criteria. The determination of the "diminished capability of the network to produce an output of metabolic interest" does not provide a tangible result that is useful to one skilled in the art. Rather, the instant claims could merely encompass *in silico* data manipulation

Art Unit: 1631

with no specific output, such as output to a user. The tangible requirement does require that the claim must recite more than a 101 judicial exception, in that the process claim must set forth a practical application of that 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because no “substantial practical application.”). In the instant case, no real-world result is set forth.

2. Applicant argues by citing *In re Lundgren*, B.P.A.I. Case Nos. 2003-2088 (Sept. 28, 2005) (*Per Curiam*). Applicant is directed to the above statements in regard to the two-fold analysis of a practical application. In the instant case, the claim fails to provide a physical transformation OR a concrete, tangible, and useful result.

3. Applicant argues that the claim provides a useful, concrete, and tangible result and requests the Office to clarify “why the claims do not constitute a practical application”. Applicant is directed to the statements above regarding tangible result.

4. Applicant argues that the claimed invention provides the result of “producing an altered network that determines a minimal deletion set which diminishes the capability of the network to produce an output metabolite of interest”. Applicant argues that the claimed method provides this “minimal deletion set which corresponds to therapeutic or bioproduction targets”.

This is not persuasive, as the claim result is not the altered network, but the determining of the reaction flux diminishing the network capability. The result provided is not concrete, tangible, and useful, as one of skill in the art would not know what real-world result is provided by the determination of reaction flux to diminish the network capability. Furthermore, the claims are not directed to a minimal deletion set corresponding to therapeutic or bioproduction targets, and thus, further lack a concrete, tangible, and useful result.

The Examiner asserts that the result is not specifically recited in the claims so as to convey a concrete, tangible and useful result, nor does the result flow inherently therefrom. Therefore, the claims remain rejected as containing non-statutory subject matter.

It is noted that in order to facilitate prosecution, this rejection could be overcome by amending the claims to recite that a result of the method is “displayed” or “outputted” (e.g. output to a user, a display, a memory, or another computer, etc.), or by amending the claims to include a step of a physical transformation of matter (e.g. assay). For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejections set forth below are necessitated by amendment.

Claim 1 recites, “wherein the determined reaction sets”. There is insufficient antecedent basis in the claim for this limitation. The claim recites “identify deletion sets” at line 12 and “determining if said eliminated internal flux diminishes the capability of the network” at lines 20-22, however, the claim does not recite “a determined reaction set”. Does Applicant intend that the “determined reaction set” is the “deletion set” of line 12? Clarification is requested.

Art Unit: 1631

Claim 2 recites, "after determining the sets of reactions". There is insufficient antecedent basis in the claim for the "determining of sets" therefore, this step is unclear as to what it further limits. See rejection above. Clarification is requested.

Claim 6 recites, "the analyzed biochemical production network". There is insufficient antecedent basis for the "analyzed biochemical production network" as there is no such network that is analyzed in claim 1. Claim 1 is directed to a method of analyzing the production of one or more metabolites of interest. However, there is no step in which an "analyzed biochemical production network" is produced. Clarification is requested.

Conclusion

No claims are allowed.

The rejections under 35 USC 101 are maintained for the reasons set forth above.

The outstanding rejections under 35 USC 112, 2nd paragraph have been overcome in view of the amendments to the claims. However, new rejections, set forth above, and necessitated by amendment, now apply.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1631

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

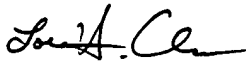
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.


Patent Examiner

January 19, 2007
Lori A. Clow, Ph.D.
Art Unit 1631